Supreme Court, U.S.
FILED
SEP 24 2003
OFFICE OF THE CLERK

(3)

No. 03-114

IN THE

Supreme Court of the United States

SOUTH CAROLINA MEDICAL ASSOCIATION, *et al.*,

Petitioners,

v.

TOMMY G. THOMPSON, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF OF GUENTER L. SPANKNEBEL, M.D., WAYNE B. GLAZIER, M.D., ABRAHAM HADDAD, D.M.D., ROBERT LEBOW, M.D., LEONARD MORSE, M.D., KESHAV PANDEY, M.D., MARK SIMONEAU, MEDICAL SOCIETY OF THE STATE OF NEW YORK, AND ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED?[1]

1. May Congress ignore the Constitution's procedural and substantive requirements when it delegates "legislative" authority?

2. Does the "Intelligible Principles Test" have a fourth element?

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1. Included within the questions presented are the following subsidiary questions: (1) Under HIPAA's § 264, does the self-imposed time limit to enact health privacy legislation statutorily alter the lawmaking process? (2) May rulemaking supplant the legislative process? (3) Does a court violate the Separation of Powers Doctrine by contradicting the plain meaning of a statute? (4) May an agency or executive department construe a statute by ignoring its plain meaning? (5) Can the 104th Congress delegate its power during a later Congress? (6) Under HIPAA's § 264, did Congress set any policy or standard to limit HHS authority?

Given the 20 page limit on the length of this brief, other related subsidiary questions are omitted. However, *amici* respectfully ask the Court for the opportunity to fully brief those questions on the merits and the opportunity to discuss various unintended consequences of the regulatory scheme. The additional questions include:

- In an electronic age, is beneficial ownership and legal title to a medical record and genetic information merged in the patient?
- Is the right to keep patient-physician communications confidential so basic a right that our nation's founders and John Locke would have considered it a fundamental or inalienable right of every individual, if they had taken the time to consider it? The founders included at least three physicians who signed the Declaration of Independence (Drs. Benjamin Rush, Josiah Bartlett, and Matthew Thornton. Some historians question the medical credentials of another signer, Lyman Hall). *See* Richard F. Corlin, M.D (President, American Medical Association), *History Repeats: Physicians Face Another 5.4% Issue* (Amednews.com,April 15, 2002) @ *www.ama-assn.org/sci-pubs/amnews/amn_02/edca0415.htm.* John Locke was a physician whose writings provide a substantial part of the Constitution's intellectual and philosophical foundation. *See e.g.*, John Locke, *Two Treatises of Government* (1698);
- Does health privacy legislation fall under the Commerce Clause?
- Is the "right to privacy" an outer boundary on the Commerce Clause?

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Cited Authorities

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Congressional Materials:

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Executive Materials:

64 Fed. Reg. 59918 *et seq.* (1999) 4, 12

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Law Reviews:

Steven F. Huefner, *The Supreme Court's Avoidance of the* NonDelegation Doctrine in Clinton v. City of New York: *More than "A Dime's Worth of Difference"*, 49 Catholic Univ. L. Rev. 337 (2000) 13

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Alan B. Morrison, *A Non-Power Looks at Separation of Powers*, 79 Geo. L.J. 281 (1990) 16

Cited Authorities

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Books and Treatises:

Black's Law Dictionary (5th ed. 1979) 9

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Joseph Story, *Commentaries on the Constitution of the United States* (Carolina Academic Press) Book III 16

Webster's Third New International Dictionary of the English Language - Unabridged (P. Gove ed. 1993) 12

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INTERESTS OF *AMICI CURIAE*[1]

Critical to the care of every patient is the patient's confidence that personal or private information communicated to the provider will be kept in confidence. This ensures that the patients will candidly communicate their conditions and history to their providers.

Amici are prominent members of the medical, dental and business communities in Massachusetts (collectively, *"Individual Amici"*), Medical Society of the State of New York ("MSSNY") and Association of American Physicians and Surgeons, Inc. ("AAPS"). *Amici* have a strong interest in protecting the confidentiality of patient-physician communications. Although *Individual Amici* are active in various medical associations and institutions, they submit this brief as individual providers and patients and not on behalf of any other entity.

Amici believe the privacy regulations issued by the United States Department of Health and Human Services ("HHS") (the "Regulations") pursuant to § 264 of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 *et seq.* (August 21, 1996) ("HIPAA")[2] compromise the trust inherent in the patient-physician relationship and reduce patient candor resulting in increased diagnostic and treatment risks. Because the Regulations contain broad exceptions to consent and authorization requirements and ignore the confidentiality principles attributed to Hippocrates approximately 2,400 years ago, *Amici* believe the Regulations shake the very foundation of the medical profession – the trust between a patient and his or her physician. *Amici* believe they can be of particular assistance to the Court regarding the nature and importance of the patient-physician relationship.

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1. In compliance with Supreme Court Rule 37.6, this brief was not written in whole or in part by counsel for a party, and no person or entity other than *Amici Curiae* and their counsel has made any monetary contribution to the brief's preparation and submission. The parties have consented to the filing of this brief, and such consents are being submitted herewith.

2. Unless otherwise specified all "section" or "§" references refer to HIPAA.

As providers and patients, *Amici* disagree with the substance of certain privacy regulations. However, as friends of this Court, *Amici* question the very power and process by which Congress purportedly authorized HHS to issue the Regulations. *Amici* ask the Court to protect Congress from itself by preserving the integrity of the "single, finely wrought and exhaustively considered, procedure", *Immigration and Naturalization Service v. Chadha*, 462 U.S. 919, 951 (1983), used to enact legislation.

Because the existence of the power of HHS to regulate health privacy is at issue, no further regulatory or judicial experience is needed before *certiorari* is warranted. In fact, delaying the grant of *certiorari* could damage thousands, if not millions, of patients. In the age of the Internet, electronic records may be transmitted and retransmitted worldwide in an instant. This means that an inadvertent or intentional release of patient information in an institutional setting could endanger the records of thousands of patients at a time. Coupling the rapidly evolving technological landscape with HHS' exceptions to the consent and authorization requirements for "payment, treatment or healthcare operations" creates a recipe for disaster for three reasons. First, most patients have at least some part of their insurance claims or medical records transferred electronically. Second, as HHS continues to implement various HIPAA standards (regarding privacy and other subjects) more and more medical institutions and providers are going "electronic" to process claims and keep patient records. Third, once the records are released, it is often too difficult or impossible to reverse the breach of privacy.

Amicus Guenter L. Spanknebel, M.D., privately practices gastroenterology and is a Past-President of the Massachusetts Medical Society ("MMS"), the nation's oldest medical society. For the past thirty-five years, he has been on the faculties of the medical schools at the University of Massachusetts and Tufts University. Dr. Spanknebel serves on various boards and committees of organized medicine.

Amicus Leonard Morse, M.D., practiced internal medicine/infectious diseases for more than 35 years. He is the immediate past chair of the Council on Ethical and Judicial

Affairs of the American Medical Association and a past President of MMS. He is President of Boston Medical Library, Professor of Clinical Medicine at University of Massachusetts Medical School, and Commissioner of Public Health for Worcester, Massachusetts. He has stated:

> [a] trusting patient-physician relationship is the fundamental beginning for appropriate health care. It is a privilege and an enormous responsibility to be a physician. In my office, all personal medical information is private, and as such, remains concealed. Nothing is released without the patient's and my approval (in that order).

Leonard Morse, Comments from Physicians, in Massachusetts Medical Society, *Background: MMS Policy on Patient Privacy and Confidentiality: Health Policy* (10/14/2000).

Amicus Wayne B. Glazier, M.D., privately practices urology. He is Chairman of the Health Foundation of Central Massachusetts and President of the Massachusetts Independent Physicians' Association.

Amicus Abraham Haddad, D.M.D., practices periodontology. He is on the faculties at Harvard School of Dental Medicine and the University of Massachusetts Medical School. He is former President of the Massachusetts Periodontal Society and former Chairman of Dental Medicine at the University of Massachusetts Memorial Hospital.

Amicus Robert Lebow, M.D., practices internal medicine. He is a trustee of MMS, Chief of Internal Medicine at Harrington Memorial Hospital and on the faculty at University of Massachusetts Medical School.

Amicus Keshav Pandey, M.D., privately practices gastroenterology. He is Assistant Professor of Internal Medicine at the University of Massachusetts Medical School and is a staff gastroenterologist at University of Massachusetts Memorial Hospital.

Amicus Mark Simoneau is the Director of Human Resources for a 500 person self-insured company located in Massachusetts. His employer is typical of thousands of other self-insured businesses throughout the country that must now

devote significant time and financial resources to comply with the Regulations.

Amicus MSSNY is a New York Not-for-Profit Corporation organized in 1807. It is a voluntary association of approximately 27,000 physician, medical resident, and medical student members. MSSNY is the principal professional organization in New York, representing physicians in all specialties. It is concerned that the enormous burdens placed by the Regulations will severely strain the ability of many medical practices to provide quality medical care and will take precious time and financial resources away from patient care.

Amicus AAPS is a nationwide non-partisan professional association of thousands of physicians in all types of practices and specialties. Since it was founded in 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship.

Amici believe that unless the decisions below are immediately reversed, Joint Appendix of Petition at A1 and A18, HHS will continue to act without legislative authority and will thereby permanently alter the nature of the medical practice. *Amici* respectfully but fervently ask the Court to grant the petition.

STATEMENT OF FACTS

Section 264 is an attempt to delegate to the Secretary of HHS the authority to issue health privacy regulations in the event that Congress failed to enact health privacy legislation within three years of HIPAA's enactment.[3] Section 264(c)(1) directed HHS to promulgate regulations governing standards with respect to the privacy of individually identifiable health information ("IIHI") if Congress did not enact health care privacy legislation by August 21, 1999. 110 Stat. at 2033. Congress did not pass privacy legislation by that deadline. On November 3, 1999, HHS published proposed health privacy regulations. 64 Fed. Reg. 59918 *et seq.* After an extended comment period, the final health privacy regulations were issued in December 2000 ("Regulations"), 65 Fed. Reg. 82462

3. Section 264 was not codified. It appears as a note to 42 U.S.C. § 1320d-2.

et seq. (December 28, 2000), and became effective on April 14, 2001, 66 Fed. Reg. 12434 (February 26, 2001)[4].

SUMMARY OF ARGUMENT

Acting without Congressional authority, HHS has changed the rights of every patient and every provider and obliterated more than 2,000 years of accepted medical practice.

Section 264(c) violates the Constitution's bicameral and presentment requirements in two ways. First, it statutorily amended the Constitution's lawmaking requirements by adding a time constraint to Article I, § 7. Second, Congress ignored the teachings of *Immigration and Naturalization Service v. Chadha*, 462 U.S. 919 (1983) and authorized regulations to supplant legislation without fulfilling the bicameral and presentment requirements.

Section 264(c) also violates the Separation of Powers Doctrine in two ways. First, courts may not construe a statute to contradict the words agreed to by both Houses of Congress and the President. Section 264 sets a deadline for HHS to act – 42 months after enactment of HIPAA. That date came and went without privacy regulations being finalized. Second, the Separation of Powers Doctrine and Execution Clause prevent HHS from presenting a construction of a statute that contradicts the words enacted by Congress and the President.

The Court should find that the delegation was defective because the principle that Congress may only delegate power it received from the people adds a fourth component to the "intelligible principles" test. First, the 104th Congress was powerless to effect a delegation beyond the expiration of its term. Second, Congress did not provide a general policy or boundary to limit the Regulations. In fact, Congress allowed HHS to address an infinite number of subjects.

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4. After the Plaintiff's Complaint was filed, HHS proposed and finalized modifications to the Privacy Regulations. 67 Fed. Reg. 14776 *et seq.* (March 27, 2002) and 67 Fed. Reg. 53182 *et seq.* (August 14, 2002) ("Modifications"). The arguments set forth herein apply to the Modifications as well as the Regulations. Indeed, the Modifications may have a greater chilling effect on patient-physician communications than the Regulations because exceptions to the consent and authorization requirements have been created for payment, treatment and healthcare operations. *Id.*

ARGUMENT

I. Section 264 Unconstitutionally Amends The Lawmaking Process By Limiting The Time For Congress To Pass A Law

Since our nation was founded more than 200 years ago, a "single, finely wrought and exhaustively considered, procedure" has been used to enact federal legislation. That procedure is laid out in the Constitution's Bicameral and Presentment Clauses. Strict compliance with those procedures is required. When Congress delegates its lawmaking function to another branch or independent agency it may not legislatively alter that process. If it does, the delegation is unconstitutional. For example, the legislative veto and the line item veto were declared unconstitutional. *Immigration and Naturalization Service v. Chadha*, 462 U.S. 919 (1983); *Clinton v. City of New York*, 524 U.S. 417 (1998). Similarly, when Congress conditions the delegation of its lawmaking function upon the restriction of its own time to consider legislation, it alters the legislative process. Section 264(c) contains such a delegation.

The Bicameral and Presentment Clauses require passage of exactly the same text by both Houses and presentment to the President. *Clinton*, 524 U.S. at 448. Those procedures may not be statutorily supplemented or modified. They may be altered only by a constitutional amendment. *Clinton*, 524 U.S. at 449; *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 837 (1995); *Oregon v. Mitchell*, 400 U.S. 112, 128 (1970). Section 264(c) alters the procedure without ratifying a constitutional amendment in accordance with Article V. Pursuant to § 264(c), once three years had elapsed without passage of new health privacy legislation, HHS had six months to regulate (unless the House, Senate and the President had agreed otherwise). In contrast, without § 264(c), HHS could not have regulated health privacy unless the House, Senate and President agreed on new health privacy legislation.

A law such as § 264(c), which completely delegates legislative responsibility to an executive department or independent administrative agency, violates the Constitution's letter and spirit. Lawmaking under the guise of rulemaking involves neither agreement of both Houses nor presentment

to the President. Section 264(c) failed to provide HHS with rulemaking authority with respect to the privacy of IIHI upon and immediately after enactment. Rather, § 264(c) provided that such rulemaking authority might later pass to HHS. That authority would pass to HHS only if legislation with respect to that subject matter failed to be enacted by the statutory deadline.

The abdication of Congressional responsibility encouraged by § 264(c) is philosophically at odds with the Constitution. *Clinton*, 524 U.S. at 452 (Kennedy, J., concurring) ("Abdication of responsibility is not part of the constitutional design"). Section 264(c) turns delegation on its head and conditions rulemaking authority solely upon the failure of Congress to take action between two specified dates. It allows Congress to avoid tough decisions. As a result, the scope of delegation was set by HHS rather than by agreement of both Houses and the President.

II. Congressional Lawmaking Is Supplanted By HHS Privacy Regulations

Although not every action taken by Congress is subject to the bicameralism and presentment requirements, those requirements must be met when Congress exercises legislative power. Whether particular actions are an "exercise of legislative power depends not on their form but upon 'whether they contain matter which is properly to be regarded as legislative in its character and effect.'" *Chadha*, 462 U.S. at 952 *quoting* S. Rep. No. 1335, 54th Cong., 2d Sess., 8 (1897).

The legislative character of an action may be established by an examination of the Congressional action that it supplants. This "Supplantation Principle" was used to analyze the constitutionality of the legislative veto in *Chadha*. *Id.* at 952 ("The legislative character of the one-House veto in these cases is confirmed by the character of the Congressional action it supplants"). That principle should be extended to apply to actions undertaken by independent agencies and other branches of government. There is no reason not to extend this principle to evaluate non-Congressional exercises of legislative power.

In *Chadha*, the constitutionality of the legislative veto provision in § 244(c)(2) of the Immigration and Nationality Act was examined. The Supreme Court examined § 244(c)(2) and found that it had an essentially legislative purpose and effect. Although the Court acknowledged that § 244(c)(2) authorized one house, by resolution, to require the Attorney General to deport an alien whose deportation otherwise would be canceled under § 244, the Court reasoned that "the House took action that had the *purpose and effect of altering the legal rights, duties, and relations of persons*, including the Attorney General, Executive Branch officials and Chadha, all outside the Legislative Branch." *Chadha*, 462 U.S. at 952 (emphasis added). The Court explained that without the House's action, Chadha would remain in the United States. Congress had acted and that action had altered Chadha's status. Without the challenged provision, Chadha's deportation could have been deported only by legislation requiring deportation, if at all. *Id.* at 953-54.

The Court also examined the nature of the decision implemented by the legislative veto. "After long experience with the . . . private bill procedure, Congress . . . [chose] to delegate to the . . . Attorney General, the authority to allow deportable aliens to remain in this country in certain specified circumstances." *Id.* at 954. The Court stated that the choice to delegate was

> precisely the kind of decision that can be implemented only in accordance with the procedures set out in Art. I. Disagreement with the Attorney General's decision on Chadha's deportation – that is, Congress' decision to deport Chadha – no less than Congress' original choice to delegate . . . involves determinations of policy that Congress can implement in only one way; bicameral passage followed by presentment to the President. Congress must abide by its delegation of authority until that delegation is legislatively altered or revoked.

Id. at 954-55.

Section 264(c) is legislative in both character and effect in two ways. First, by its own terms, it is equivalent to legislation. The alleged authority of HHS to promulgate regulations arose only after Congress failed to pass legislation governing standards with respect to the privacy of IIHI within 36 months of the enactment of HIPAA. Second, the Regulations had the purpose and affect of altering the rights, duties, and relations of persons, including patients, providers, health care clearinghouses, health plans, HHS, Office of Civil Rights and others, all outside of Congress. Section 264(c)(1) ("Such regulations shall address at least the subjects described in subsection (b)").

Subsections "a" and "b" reinforce this conclusion. They directed the Secretary of HHS to make legislative recommendations regarding privacy of IIHI. They set a limited agenda for the Secretary: to make recommendations for future legislation. The difficult policy choices regarding rights, procedures, and uses and disclosure of IIHI were left to Congress. Subsection "a" explicitly directed the Secretary of HHS to submit "detailed recommendations on standards with respect to the privacy of [IIHI]." Those recommendations were to be received by a Senate Committee and a House Committee. As used, the word "recommendations" contemplated future Congressional action. In the context of § 264, "recommendations" were sought solely for a legislative purpose - to propose and possibly enact future legislation. The subjects contained in § 264(b) are legislative in nature and include the rights an individual should have, § 264(b)(1), the procedures for exercising those rights, § 264(b)(2), and the determination of permitted "uses and disclosures", § 264(b)(3).[5] If Congress had enacted the recommendations with respect to those rights, everyone in the United States would have been affected. Similarly, the Regulations affect everyone in the United States - people and parties outside Congress.

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5. A "right" is "[a] power, privilege, or immunity granted under a constitution, statutes, or decisional laws, or claimed as a result of long usage" or "[a] legally enforceable claim of one person against another, that the other shall do a given act, or shall not do a given act." *Black's Law Dictionary* 1189 (5th ed. 1979).

The language seeking recommendations from HHS set forth in Subsections "a", "b", and "d", as well as the language of Subsection "c", suggests that no laws governing privacy standards existed when HIPAA was enacted or prior thereto. Congress wrote on a blank slate. It needed to be better informed before legislating. This understanding is consistent with Subsections "a", "b", and "d" under which Congress explicitly sought recommendations from HHS regarding those standards. Subsections "a", "b", and "d" reveal that Congress had not yet made any policy determination or value judgment regarding the standards for privacy of IIHI when it enacted HIPAA. Marci Hamilton, *Representation and NonDelegation: Back to Basics*, 20 Cardozo L. Rev. 807, 820 (1999) ("The legislature holds primary responsibility to make the national policy choices, and the President may not take on those choices."); *See Clinton*, 524 U.S. at 442-45, 445 n.38. Congress had not balanced the interests of various constituencies regarding that subject matter.[6] However, Congress had recognized that it needed further advice. Consequently, HHS rulemaking authority under § 264(c) was equated to legislation and *carved-out from the remainder of § 1173 rulemaking authority.*[7]

6. Institutionally, Congress is better able to balance multiple viewpoints than a single agency or department. *See* Hamilton, 20 Cardozo L. Rev. at 814

> The legislative branch serves the people by filtering the factions in the society and distilling those laws that will best serve the nation . . . [P]ositions must be funneled through a large number of ports before becoming governing law . . . As a result, it is capable of reaching more nuanced compromises on national issues.

In contrast, when lawmaking is delegated to the President, there is only one port of entry, one viewpoint, albeit representing the entire nation. When lawmaking is delegated to an agency or executive department, the viewpoint is even narrower and without electoral accountability. *Id.* at 819-21. The best evidence of why there should be a Congressional filter and why Congress should set national policy is the fact that HHS received approximately 52,000 comments in connection with its issuance of the Regulations. 67 Fed. Reg. at 14777.

7. 65 Fed. Reg. at 82469-70. Section 1173 authorized HHS to promulgate uniform national standards regarding transactions, unique health identifiers, code sets, security and electronic signatures. Section 1173 of the Social Security Act, 110 Stat. 2024-26 *codified* at 42 U.S.C. § 1320d-2. In conference, privacy of IIHI was moved out of § 1173.

III. The Courts Below Violated The Separation Of Powers Doctrine By Construing § 264(c) To Eliminate The Statute's Deadline For HHS Action

Petitioners and Respondents placed the construction of § 264(c) at issue in District Court and Court of Appeals. The opinions reflect this concern. Joint Appendix of Petition, A1 and A18. Petitioners ask this Court to consider § 264(c)'s plain meaning. Petition 20-26. However, the parties and courts below have all ignored part of sentence 1 of § 264(c)(1) in construing the remainder of the sentence. The ignored language involves the 42 month deadline on HHS authority to issue the Regulations. That date came and went before the Regulations were finalized. By permitting HHS to regulate after the deadline, the courts below "rewrote" the statute instead of applying the Plain Meaning Rule.

Under the Separation of Powers Doctrine, courts lack power to rewrite statutes. Our nation's founders considered and expressly rejected the idea that Judges join with the Executive in a "Council of Revision". Brief of Senators Robert C. Byrd, Daniel Patrick Moynihan and Carl Levin as *Amici Curiae* in Support of Appellees 9-10 in *Clinton v. City of New York* (Docket No. 97-1374).

Section 264(c)(1) specifically and unambiguously limited the authority of HHS to promulgate final regulations to a date that is "*NOT LATER THAN THE DATE* that is 42 months after the date of the enactment of this Act."[8] Issuing the Regulations after that date conflicted with § 264(c)(1). Additional legislation was required for HHS to have issued final regulations after February 21, 2000. Congress did not enact any extension. It is not ambiguous as to whether § 264(c)(1) required "proposed" or "final" regulations by the deadline. The plain meanings of "final' and "not later than the date that is 42 months . . ." are unmistakable. The Secretary was not directed to promulgate *PROPOSED* regulations by that date. Section 264(c)(1) directed the Secretary to promulgate *FINAL* regulations by the specified date. The adjective "final" modifies the noun "regulations". This eliminates the possibility of having an implied

8. Section 264(c)(1) (emphasis added). This is a date certain once HIPAA was enacted. That date is not subject to the discretion of the Secretary of HHS.

modification of the noun "regulations" by the adjective "proposed". "Final" means "not to be altered or undone". *Webster's Third New International Dictionary of the English Language – Unabridged* 851 (P. Gove ed. 1993).

When § 264(c)(1) is analyzed, the words "not later than" are not ambiguous. They are an absolute bar to HHS action after that date. Under the Constitution's first clause, legislative power is vested in Congress. This means that Congress alone "writes" the laws – subject only to a Presidential veto. A flexible interpretation of the words "not later than" would rewrite their apparent meaning.

The distinction between "final" and "proposed" regulations is found in the statement accompanying the release of the Regulations in December of 2000: "As the Congress did not enact legislation regarding the privacy of [IIHI] prior to August 21, 1999, HHS published *proposed* rules setting forth such standards on November 3, 1999, 64 Fed. Reg. 59918, and is *now publishing* the mandated *final* regulation." 65 Fed. Reg. at 82470 (emphasis added). This language shows that HHS understood that "final regulations" had not existed before December 2000.

The "Plain Meaning Rule" is one of several canons of construction applied by courts to determine the meaning of legislation. Courts turn to this canon before others. *Connecticut National Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there . . . When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'") (Thomas, J.) (internal citations omitted). Legislators are "presumed to know the meaning of words and the rules of grammar." *United States v. Goldenberg*, 168 U.S. 95, 102-03 (1897). The time to promulgate final regulations had lapsed. It could not have been extended without new legislation.

Chief Justice Taft aptly articulated the principle that judges are not to exercise legislative power. He said:

> it is a breach of the national fundamental law if Congress gives up its legislative power and

> transfers it to the President, or to the judicial branch, or if by law it attempts to invest itself or its members with either executive power or judicial power.

J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 406 (1928).

The Judicial Branch does not legislate. A court must apply the law as written and bicamerally passed by Congress and approved by the President. *Clinton*, 524 U.S. at 448. The courts below had no authority to eliminate "not later than the date that is 42 months after the date of the enactment of this Act". The courts had acted outside of Article III and allowed HHS to issue the Regulations *ultra vires*.

IV. The Separation Of Powers Doctrine And The Execution Clause Prevent HHS From Arguing A Construction Of § 264(c) That Contradicts Its Plain Meaning

Because HHS was powerless to act unless it ignored the 42 month deadline, it must argue that the deadline should be eliminated. HHS has taken this position elsewhere. *Association of American Physicians and Surgeons, Inc. v. United States Department of Health and Human Services*, 23 (Civ. Action No. H 01-2963) (SL) (S.D. Tex. June 14, 2002). HHS, like the courts, must defer to the law enacted by Congress and the President. Except for the President's ability to veto and to recommend legislation, the Executive Branch has no role in the legislative process. *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 587 (Black, J.) (1952) and 655 (Jackson, J., concurring). It may not rewrite, through interpretation and advocacy, words agreed to by the Senate, the House and the President. Allowing HHS to promulgate regulations or to present an argument that ignores a statute's plain meaning undermines the deference due a coordinate branch of government and gives the Executive Branch power to make law.[9]

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9. When the Secretary performed her duty, her actions could not have reached beyond the statute that created that authority. *Chadha*, 462 U.S. at 953-54 n.16 and accompanying text; *See also* Steven F. Huefner, *The Supreme Court's Avoidance of the NonDelegation Doctrine in Clinton v. City of New York: More than "A Dime's Worth of Difference"*, 49 Catholic Univ. L. Rev. 337, 404 (2000).

To have force of law, Congress must have enacted the Regulations as new legislation or have ratified the Regulations through new legislation.[10] Post-HIPAA legislation did neither. Ratification must be explicit. It may not be implied.

Implied ratification of agency or executive action creates a dispensing power and allows an agency or department to pick and choose which statutes to faithfully execute. It turns rulemaking on its head - having agency or executive actions control legislation instead of being controlled by legislation. The doctrine has no support in the Constitution. It asserts a principle which would be clothing the President and executive departments and independent agencies with "a power entirely to control the legislation of [C]ongress and paralyze the administration of justice." *Kendall v. United States ex rel. Stokes*, 12 Pet. (37 U.S.) 524, 613 (1838) (The Court firmly rejected the contention that the President's duty "to see the laws faithfully executed, implies a power to forbid their execution")[11]. Allowing HHS to ignore the time constraint on issuing final regulations is the equivalent of empowering HHS to forbid execution of a statute. So is allowing HHS to argue that the constraint should be ignored.

Even if issuing the Regulations is viewed as "interstitial lawmaking", it is impermissible. The Supreme Court has long allowed the practice of interstitial lawmaking. *Wayman v. Southard*, 10 Wheat. (23 U.S.) 1, 43 (1825) (Marshall, J.). However, the Court has not allowed interstitial regulations to conflict with the authority provided by statute. More than a century ago, the Court struck down an order of the Secretary of the Navy that directed that a particular training vessel was not to be considered "at sea" in connection with an officer's compensation for sea service. According to the Court, the Secretary did not have authority to declare something as "shore duty" that the statute requires the Navy to treat as "sea duty".

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10. Although Congress could have extended the time for HHS to issue the "final regulations", it failed to do so.

11. Additionally, Congress "may not 'invest itself or its Members with either executive power or judicial power.'" *See Metropolitan Washington Airports Authority v. Citizens for the Abatement of Aircraft Noise, Inc.*, 501 U.S. 252, 274 (1991); *see also Hampton*, 276 U.S. at 406.

The Court declared that the Secretary only had authority to "establish regulations in execution of, or supplementary to, *but not in conflict with*, the statutes defining his powers or conferring rights upon others." *United States v. Symonds*, 120 U.S. 46, 48-49 (1887) (emphasis added). Finalizing the Regulations on a date after February 21, 2000 is in direct conflict with the words of § 264(c)(1) of HIPAA and must be struck down.

To the extent that *Brock v. Pierce County*, 476 U.S. 253 (1986) and its progeny,[12] suggest that a Congressionally imposed deadline on agency or executive authority is flexible, those cases ignore *Symonds* and *Kendall* and should be distinguished or overruled.

V. Congress Defectively Delegated Authority To HHS

The principle that Congress may only delegate power it received from the People adds a fourth component to the three-pronged "intelligible principles" test. It is based on two underlying concepts. First, the federal government is one of enumerated powers. Second, a principal may not delegate authority it lacks.

A. The 104th Congress Cannot Delegate Its Authority Beyond The End Of Its Own Term

Since our nation's first days, "[e]very law enacted by Congress must be based on one or more of its powers enumerated in the Constitution." *United States v. Morrison*, 529 U.S. 598, 607 (2000); *McCulloch v. Maryland*, 4 Wheat. (17 U.S.) 316, 405 (1819). Those powers are constrained by the Constitution's procedural requirements, *see, e.g.*, U.S. CONST. art. I, § 7, cl.2, and substantive requirements, *see, e.g.*, U.S. CONST. art. I, § 9. In this case, another constraint is the temporal limit on the Congressional franchise.

The President and members of the Senate and members of the House of Representatives represent different geographic constituencies, have different modes of election, and have different requirements for holding office. U.S. CONST. art. I,

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12. *See, e.g., United States v. Montalvo-Murillo*, 495 U.S. 711 (1990); *United States v. James Daniel Good Real Property*, 510 U.S. 43 (1993); *Regions Hospital v. Shalala*, 522 U.S. 448 (1998); and *Barnhart v. Peabody Coal Co.*, __ U.S. __, 123 S. Ct. 748 (2003).

§§ 2 & 3, U.S. CONST. art. II, § 1 and U.S. CONST. amend. XVII. The Constitution further diffuses power by limiting the terms of the President and members of the Senate and House of Representatives and by making those terms of different lengths, *i.e.* they have different temporal mandates. Senators are elected for six years. U.S. CONST. art. I, § 3, cls.1&2 and U.S. CONST. amend. XVII. The President is elected for four years. U.S. CONST. art. II, § 1, cl.1. Members of the House of Representatives are elected for two years. U.S. CONST. art. I, § 2, cl.1. The authority of each Representative, each Senator and the President does not extend beyond the expiration of his or her term in office, respectively.[13] Any extension of authority beyond the end of those terms would unconstitutionally transfer from the People the power of the people to choose their own representatives.[14] One commentator characterized the holding of elective offices as a "temporary lease" from the nation's citizens. Alan B. Morrison, *A Non-Power Looks at Separation of Powers*, 79 Geo. L.J. 281, 282 (1990). Expressed in real estate terms, the Constitution does not allow "holdovers".

When Congress "delegates" its power to "make law"[15], the delegation must occur before the Congressional term ends, *i.e.* the end of the term for which the House members are elected. The reasoning is simple. A principal may delegate to its agent only the authority within its possession. A principal may not delegate authority that it does not have. Each House and Senate member loses all authority from his or her

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13. *See* Joseph Story, *Commentaries on the Constitution of the United States* (Carolina Academic Press) Book III § 263.

14. George Washington said:

> The power under the Constitution will always be in the People. *It is entrusted* for certain defined purposes, *and for a certain limited period, to representatives of their own chusing;* and whenever it is executed contrary to their Interest, or not agreeable to their wishes, their Servants can, and undoubtedly will be, recalled.

Thornton, 514 U.S. at 814 n.26 (emphasis added) (internal citations omitted).

15. The power to "make law" stands in contrast to the power to "fill-in details" or otherwise "execute" legislation. *See Loving v. United States*, 517 U.S. 748, 771 (1996) (Kennedy, J.).

constituents at term-end. Consequently, the end of a Congressional term ends *subsequent legislative actions* by that Congress. Similarly, the President has no authority to sign or veto legislation once his or her term expires. If Congress, as principal, cannot exercise its legislative power, then an agent of that Congress may not exercise that power.

Section 264(c) attempts an impermissible delegation of the power to legislate beyond the end of the Congressional term. Rulemaking authority under § 264(c) was not permitted to occur upon or even immediately after enactment. Rather, it was deferred until 36 months after enactment of HIPAA. Indeed, rulemaking would not have occurred if Congress had enacted health privacy legislation within 36 months. Once the 105th Congress began in January 1997, the 104th Congress had no power. After that date, the 104th Congress had no power to legislate with respect to the standards for the privacy of IIHI or for anything else. Consequently, the agent of the 104th Congress, HHS, lacked that power as well.

B. Congress Provided No Policy or Boundary to Limit HHS Authority

Under the "intelligible principles" test, it is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Mistretta v. United States*, 488 U.S. 361, 372-73 (1989) *quoting American Power & Light Co. v. S.E.C.*, 329 U.S. 90, 105 (1946). In addition, a delegation is always subject to the legislation that authorized it. *Chadha*, 462 U.S. at 953-54 n.16.

It has been suggested that delegation to administrative agencies leaves a gaping hole in the Constitution's balanced structure of checks and balances because agencies are prone to be arbitrary and unaccountable. "The nondelegation doctrine in this scenario is crucial to liberty, because it prohibits general lawmaking from occurring in a structure both capable of arbitrary action and removed from the national scrutiny to which both Congress and the President are exposed by the constitutional structure." Hamilton, 20 Cardozo L. Rev. at 821.

Section 264(c) fails to meet two of the three "intelligible principle" criteria. First, there is no clearly delineated general policy. Second, there is no boundary on the delegated authority.

Neither the general policy statement contained in the Preamble to HIPAA nor the policy statement articulated as § 261 of the Administrative Simplification provisions of HIPAA "clearly delineates" a general policy that is applicable to the privacy of IIHI.

First, HIPAA's Preamble provides that HIPAA is:

> [a]n act to amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.

110 Stat. at 1936. Privacy of IIHI is not referable to any of the specified purposes.

The Administrative Simplification provisions comprise subtitle F of HIPAA. The first section, § 261, contains a statement of the purpose of subtitle F. 110 Stat. at 2021 (not codified but *appears* at 42 U.S.C. § 1320d note).

The argument that "standards with respect to the privacy of IIHI" is encompassed by the language appearing at the end of § 261 (*i.e.* "through the establishment of standards and requirements for the electronic transmission of certain health information") is untenable. A fair reading of that language points to § 1173, which is entitled "STANDARDS TO ENABLE ELECTRONIC EXCHANGE". It does not point to § 264, which is entitled "RECOMMENDATIONS WITH RESPECT TO PRIVACY OF CERTAIN HEALTH INFORMATION." Section 264 directed the Secretary of HHS to make recommendations. It did not direct the Secretary to establish any standard or requirement with respect to privacy of IIHI upon enactment. The only authority to issue such standards was contingent authority if Congress failed to enact legislation. The policy and purpose with respect to privacy of IIHI were

to be determined by later legislation. HIPAA contained no delineation of a policy or purpose with respect to privacy of IIHI.

Although, the Fourth Circuit concluded these provisions amount to a statement of "general policy", Joint Appendix of Petition at 8-9, the statute and Regulations do not support this conclusion. First, neither the patient nor a surrogate designated by the patient is required as a control or check point to limit information transfer. Second, HIPAA contains no private right of action for patients to protect themselves. Third, HIPAA and the Regulations do not necessarily apply to individuals and entities that wrongfully obtain IIHI. Fourth, HHS has created exceptions to the consent and authorization requirements for transactions involving payment, treatment and healthcare operations and HHS could conceivably create further exceptions in the future. Fifth, the Regulations do not apply to all of a patient's personal and medical information but only to IIHI that is within the scope of § 1173. If privacy were truly the policy, HHS would not have been able to lower the confidentiality bar from that encompassed by the Hippocratic Oath and practiced by physicians throughout our nation's history.

Section 264 provides no marker or check to determine whether HHS has exceeded the authority authorized by Congress. *See Yakus v. United States*, 321 U.S. 414, 423-24 (1944); *Chadha*, 462 U.S. at 953.

The phrase "shall address at least" is used both to list the subjects of legislative recommendations to be submitted by HHS and to list the subjects of rulemaking authority to be delegated if Congress failed to pass legislation by the statutory deadline. The use of that phrase removed all limits on HHS's authority. In *A.L.A. Schechter Poultry Corporation v. United States*, the Supreme Court struck down, as overly broad, a delegation that merely affected all industries. 295 U.S. 495 (1935). The delegation in § 264(c) is much broader. Its impact is not limited to the healthcare industry or even to all industries. It affects everyone. Its impact is pervasive.

Congress omitted boundaries from § 264 which contains a minimal set of subjects to be recommended to Congress and

a minimal set of subjects to be included in future regulations in the event that Congress does not enact legislation in connection with those recommendations by the specified future date. Because the words "address at least" appear in § 264(b) and § 264(c)(1), there is nothing in § 264 to constrain HHS rulemaking authority. There are only three subjects that must be addressed. HHS was permitted to address an infinite number of subjects.[16] In *Whitman v. American Trucking Associations, Inc.*, the Supreme Court said, "[t]he very choice of which portion of the power to exercise - that is to say, the prescription of the standard that Congress had omitted - would *itself* be an exercise of the forbidden legislative authority." 531 U.S. 457, 473 (2001) (Scalia, J.). HHS has exercised such forbidden legislative authority.

CONCLUSION

Under the Constitution, the power to make the law rests squarely in the hands of Congress. Congress may not voluntarily relinquish its basic duty - to determine what the law shall be. Section 264 of HIPAA took that role from Congress and handed it to HHS. Certiorari is warranted to protect Congress from itself.

Because compliance with the Regulations has already altered the nature of medical practice, action by the Court is needed now and not later. Unless the Court grants the petition and declares § 264 unconstitutional on the merits, patients will lose their right to keep their medical records confidential. Whether a single electronic medical record or a million such records is at issue, once confidentiality is lost, nothing can be done to restore it. Therefore, the Court should address the constitutionality of § 264 at this time.

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16. To clarify this point, we assume *arguendo* that § 264 dealt with the Department of Agriculture ("DoA") and the three subjects were regulations concerning apples, bananas and celery. Under the construction adopted by HHS and the courts below, DoA would be allowed to regulate those three items as well as an infinite number of other items (*e.g.*, dates, eggplants, figs, green beans, . . . zucchini) even if Congress and the President never agreed to regulate any item that DoA ultimately regulated.

Respectfully submitted,

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